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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,967	05/08/2001	Stuart A. Newman	51230-00601	1338

25243 7590 07/30/2003

COLLIER SHANNON SCOTT, PLLC
3050 K STREET, NW
SUITE 400
WASHINGTON, DC 20007

EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/30/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/849,967

Applicant(s)

NEWMAN ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

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-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 21, 29-36 and 43-64 is/are pending in the application.
- 4a) Of the above claim(s) 31-36 and 43-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 21, 29, 30, and 55-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

This application contains claims 31-36, 44-54 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 31-36, and 43-54 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Claims 1-15, 21, 29-36, and 43-64 are pending and claims 1-15, 21, and 55-64 are examined on merits.

Claim Objections

The objection of claim 21 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 112

The rejection of claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of amendment.

Claims 1-15, and 29-36 remain rejected for reason of record under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of modifying activity of hnRNP A proteins, does not reasonably provide enablement for method of modifying activity of any other nucleotide binding proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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Applicant argues that some of the claims are amended, and some cancelled to obviate the rejection. However, the amended claims are still drawn to method of modifying the activity of various nucleotide binding proteins by introducing **a genus of polynucleotides that are substrate for said** various nucleotide binding proteins. Applicant does not address this issue.

The rejection of claim 5 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn because applicant argument is persuasive.

The rejection of claim 13 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn because applicant argument is persuasive.

Claim Rejections - 35 USC § 102

Claims 1, 3, 6, 11, 15, 29, and 30 remain rejected and the new claims 55-58 are also rejected for reason of record under 35 U.S.C. 102(b) as being anticipated by **Blanchette et al** (Apr 1, 1999, The EMBO Journal, vol. 18, pages 1939-1952).

Applicant argues that the substrate for the proteins in the art of record is cis-acting elements while the claimed invention is drawn to method using trans-acting element. This and other argument is not persuasive because applicant argues with limitation not present in the claims. The claims say "a plurality of polynucleotide sequences" as long as said polynucleotides modify activity of splicing regulatory proteins.

Claims 1, 3, 6-8, 10-12, 14, and 15 remain rejected and the new claims 55-58 are also rejected for reason of record under 35 U.S.C. 102(b) as being anticipated by **McNally et al** (Mar. 1999, Journal of Virology, vol. 73, pages 2385-93). Applicant argues that the substrate for the proteins in the art of record is cis-acting elements while the claimed invention is drawn to method using trans-acting element. This and other argument is not persuasive because applicant argues with limitation not present in the claims. The claims say "a plurality of polynucleotide sequences" as long as said polynucleotides modify activity of splicing regulatory proteins.

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The rejection of the claims under 35 U.S.C. 102(b) as being anticipated by **Caceres et al** (1998, Genes Dev., vol. 12, pages 55-66) is withdrawn because applicant argument is persuasive.

Claim Rejections - 35 USC § 103

Claim 9 remain rejected for reason of record under 35 U.S.C. 103(a) as being unpatentable over Blanchette et al (Apr 1, 1999, The EMBO Journal, vol. 18, pages 1939-1952) as applied to claims 1, 3, 6, 11, 15-18, 20, 22-30, 37-42 above, and further in view of Ross et al (1997, Molecular And Cellular Biology, vol. 17, pages 2158-2165).

Applicant argues that the primary reference does not teach the instantly claimed invention because the substrate of the primary reference is cis-acting while instant invention is drawn to trans-acting. This argument is not persuasive because applicant argues with limitation not present in the claims.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 102

Claims 55, 56, and 61-64 are rejected under 35 U.S.C. 102(b) as being anticipated by anticipated by **Muro et al** (Mol Cell Biol. 1999 Apr;19(4):2657-71).

The claims are interpreted as drawn to modifying splicing regulatory proteins' activity in the cell using exonic splicing enhancers (ESE) or ESS. Muro et al teach method of modifying splicing regulatory proteins' activity using exonic splicing enhancers. See Materials and Method at page 2658, abstract, and Figs. 7.

Claims 55, 56, 59, 60 are rejected under 35 U.S.C. 102(b) as being anticipated by anticipated by **Hastings et al** (J Biol Chem. 2000 Apr 14;275(15):11507-13).

The claims are interpreted as drawn to modifying splicing regulatory proteins' activity in the cell using intronic splicing enhancers. Hastings et al teach method of modifying splicing regulatory proteins' activity using intronic splicing enhancers. See Materials and Method at page 11508 especially Figs. 3.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
July 28, 2003


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600